

## **902 KAR 20:275. Mobile health services.**

RELATES TO: KRS 216B.010-216B.131, 216B.990, 311, 313, 314, 319A, 327, 334A, 29 C.F.R. 1910.1030(d)(2)(vii), 45 C.F.R. 160, 164, 42 U.S.C. 1320d

STATUTORY AUTHORITY: KRS 216B.042

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.042 requires the Cabinet for Health and Family Services to promulgate administrative regulations necessary for the proper administration of the licensure function, which includes establishing licensure standards and procedures to ensure safe, adequate, and efficient health facilities and health services. This administrative regulation establishes the minimum licensure requirements for the operation of and services provided by mobile health services.

Section 1. Definitions. (1) "Computed tomography (CT) scanning" means a radiological diagnostic imaging procedure that shows cross sectional images of internal body structures.

(2) "Governing authority" or "licensee" means the individual, agency, partnership, or corporation in which the ultimate responsibility and authority for the conduct of the institution is vested.

(3) "IV therapy" means the administration, by a registered nurse under the supervision of a licensed physician, of various pharmaceutical and nutritional products by intravenous, subcutaneous, or epidural routes.

(4) "IV therapy service" means pharmaceutical and nursing services, including direct hands-on care, limited to and necessary for the:

(a) Preparation, dispensing, and delivery of pharmaceutical and nutritional products and equipment; and

(b) Related clinical consultation, training, and assessment or care incidental to initial start-up of IV therapy.

(5) "License" means an authorization issued by the cabinet for the purpose of operating mobile health services.

(6) "Lithotripter" means a noninvasive treatment technique that utilizes shock waves to shatter kidney stones.

(7) "Magnetic resonance imaging" or "MRI" means a diagnostic imaging modality which utilizes magnetic resonance, an interaction between atoms and electromagnetic fields, to project images of internal body structures.

(8) "Other diagnostic and treatment services" means those health services which are determined to require licensure pursuant to KRS 216B.042 as a mobile health service.

(9) "Positron emission tomography scanning" or "PET scanning" means an imaging procedure that uses a radioactive substance to reveal how organs and tissues are working.

(10) "Qualified anesthesiologist" means a person who:

(a) Is a doctor of medicine or a doctor of osteopathy licensed to practice medicine and surgery;

(b) Is board certified or in the process of being certified by the American Board of Anesthesiology or the American Osteopathic Board of Surgery; and

(c) Meets the criteria established by the mobile health service's governing authority.

(11) "Qualified urologist" means a person who:

(a) Is a doctor of medicine or a doctor of osteopathy licensed to practice medicine and surgery;

(b) Is board certified or is in the process of being certified by the American Board of Urology or the American Osteopathic Board of Surgery; and

(c) Meets criteria established by the mobile health service's governing authority.

(12) "Registered nurse" is defined by KRS 314.011(5).

(13) "Therapy practice" means a practice:

(a) That does not meet the licensure exemption criteria of KRS 216B.020(2); and

(b) Employs, directly or by contract, at least one (1) or any combination of the following practitioners:

1. Occupational therapists and occupational therapy assistants licensed pursuant to KRS Chapter 319A;

2. Physical therapists and physical therapy assistants licensed or certified pursuant to KRS Chapter 327; or

3. Speech-language pathologists and speech language pathology assistants licensed pursuant to KRS Chapter 334A.

Section 2. Scope of Operation and Services. (1) Mobile health services:

(a) Shall provide medical services in various locations, which may include settings such as the office of the licensee, a health facility licensed under KRS Chapter 216B, or a home- or community-based setting; and

(b) May utilize a specially equipped vehicle, including a:

1. Van;

2. Trailer; or

3. Mobile home.

(2) A mobile health service shall not include a private office or entity exempt from licensure pursuant to KRS 216B.020(2).

(3) Mobile health services shall include:

(a) Mobile diagnostic imaging and examination services; or

(b) Mobile treatment services.

(4) Mobile health services may be:

(a) Provided through the use of a mobile vehicle; or

(b) Performed at various locations.

Section 3. Administration. (1) Licensee.

(a) The licensee shall be legally responsible for:

1. All activities of the mobile health service; and

2. Compliance with federal, state, and local laws and administrative regulations pertaining to the operation of the service, limited to the scope of the service's certificate of need.

(b) The licensee shall:

1. Establish lines of authority; and

2. Designate an administrator who shall be principally responsible for the daily operation of the service.

(2) If a mobile health service's governing authority is comprised of more than one (1) licensed hospital, a separate administrator may be designated from each hospital to serve as administrator during the time in which services are provided at the hospital where the designee is employed.

(3) Policies. A mobile health service shall establish and follow written administrative policies covering all aspects of operation, including:

(a) A description of organizational structure, staffing, and allocation of responsibility and accountability;

(b) Policies and procedures for the guidance and control of personnel performances;

(c) A written program narrative describing in detail each service offered, methods and protocols for service delivery, qualifications of personnel involved in the delivery of the services, and

goals of each service;

(d) A description of the administrative and patient care records and reports; and

(e) Procedures to be followed if the licensee performs any functions related to the storage, handling, and administration of drugs and biologicals.

(4) Personnel.

(a) Medical director. Except for a therapy practice or entity that is licensed pursuant to this administrative regulation to provide only therapy services, the mobile health service shall have a medical director who shall be a licensed physician or dentist with specialized training and experience in, and responsibility for, all medical or dental aspects of the service.

(b) A mobile health service shall be exempt from paragraph (a) of this subsection if:

1. The service operates only diagnostic examination equipment;

2. The service is offered only to licensed hospitals; and

3. Personnel make no medical assessment of the diagnostic patient data collected.

(5) A mobile health service shall employ or contract with a sufficient number of qualified personnel to provide effective patient care and all other related services.

(6) The licensee shall provide written personnel policies, which shall:

(a) Be available to each employee;

(b) Be reviewed on an annual basis;

(c) Be revised as necessary; and

(d) Contain a job description for each position subject to review and revision, as necessary.

(7) The licensee shall maintain current personnel records for each employee that shall contain the following:

(a) Name, address, and Social Security number;

(b) Evidence of current registration, certification, or professional licensure;

(c) Documentation of training and experience;

(d) Performance evaluations; and

(e) Record of pre-employment and regular health exams related to employment.

(8) In-service training. Personnel shall attend training programs relating to their respective job activities. The training programs shall include:

(a) Thorough job orientation for new employees; and

(b) In-service training programs, emphasizing competence and professionalism necessary for effective health care.

(9) Medical records.

(a) The licensee shall maintain medical records that contain the following:

1. Medical and social history relevant to each service provided, including data obtained from other providers;

2. Physician's orders if an order is required for a specific diagnostic service;

3. Description of each medical visit or contact, including a description of the:

a. Condition or reason for the visit or contact;

b. Assessment;

c. Diagnosis;

d. Services provided;

e. If applicable, medications and treatments prescribed; and

f. Disposition made;

4. Reports of all physical examinations, laboratory, x-ray, and other test findings related to each service provided; and

5. Documentation of all referrals made, including reason for referral and to whom patient was referred.

(b) Ownership.

1. Medical records shall be the property of the mobile health service.
2. The original medical record shall not be removed except by court order.
3. Copies of a medical record or portions of the record may be used and disclosed, in accordance with the requirements established in this administrative regulation.

(c) Confidentiality and security: use and disclosure.

1. The mobile health service shall maintain the confidentiality and security of medical records in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 42 U.S.C. 1320d-2 to 1320d-8, and 45 C.F.R. Parts 160 and 164, as amended, including the security requirements mandated by subparts A and C of 45 C.F.R. Part 164, or as provided by applicable federal or state law.

2. The mobile health service may use and disclose medical records. Use and disclosure shall be as established or required by HIPAA, 42 U.S.C. 1320d-2 to 1320d-8, and 45 C.F.R. Parts 160 and 164, or as established in this administrative regulation.

3. This administrative regulation shall not be construed to forbid the mobile health service from establishing higher levels of confidentiality and security than required by HIPAA, 42 U.S.C. 1320d-2 to 1320d-8, and 45 C.F.R. Parts 160 and 164.

(d) Transfer of records. The licensee shall:

1. Establish systematic procedures to assist in continuity of care if the patient moves to another source of care; and
2. Upon proper release, transfer medical records or an abstract, if requested.

(e) Retention of records. After the patient's death or discharge, the completed medical record shall be placed in an inactive file and retained for:

1. Six (6) years; or
2. If a minor, three (3) years after the patient reaches the age of majority under state law, whichever is the longest.

(f) Mammography and other radiology records shall be retained in accordance with 42 U.S.C. 263b(f)(1)(G).

(g) A specific location shall be designated by the mobile health service for the maintenance and storage of the service's medical records.

(h) The licensee shall have provisions for the storage of medical records if the mobile health service ceases to operate because of disaster or for any other reason.

(i) The licensee shall safeguard the record and its content against loss, defacement, and tampering.

(j) If a therapy practice licensed pursuant to this administrative regulation provides physical therapy, occupational therapy, or speech pathology services under a contractual agreement with another facility or service licensed under 902 KAR Chapter 20, the therapy practice shall:

1. Be exempt from the requirements of this subsection; and
2. Demonstrate compliance with Section 5(3)(d)1.d. and Section 5(3)(d)3. of this administrative regulation.

(10) Kentucky Health Information Exchange (KHIE).

(a) A mobile health service shall participate in the KHIE pursuant to the requirements of 900 KAR 9:010.

(b) If a mobile health service has not implemented a certified electronic health record, the service may meet the requirement of paragraph (a) of this subsection by participating in the direct secure messaging service provided by KHIE.

Section 4. Requirements for any Vehicle that a Patient Enters for Diagnostic or Treatment Services. (1) A vehicle used for the delivery of medical or dental services shall be kept in optimum order with clean interiors and equipment.

(2) The following standards shall apply only to a vehicle in which the patient enters:

(a) There shall be adequate heating and air-conditioning capability in both the driver and patient compartments;

(b) There shall be a minimum of two (2) potential power sources for the vehicle;

(c) To insure an immediately available source of power if a power failure occurs, one (1) power source shall be self-contained on the vehicle, and the other source shall be an exterior source of power hookup;

(d) The vehicle shall be accessible to users with disabilities through the use of a wheelchair lift or a ramp; and

(e) The vehicle shall have adequate and safe space for staff and examination procedures.

(3) Equipment. A vehicle used for the delivery of health services shall have the following essential equipment:

(a) One (1) five (5) pound dry chemical fire extinguisher;

(b) One (1) first aid kit;

(c) Suction apparatus; and

(d) Oxygen equipment (portable), including:

1. One (1) "D" size oxygen cylinder;

2. One (1) pressure gauge and flow rate regulator;

3. Adaptor and tubing; and

4. Transparent masks for adults and children. Nasal cannulas may be substituted.

(4) Personnel. Each mobile health service vehicle shall be staffed by at least one (1) person, who may be the driver of the vehicle, and shall have the following qualifications:

(a) Red Cross Advanced and Emergency Care Certification, each with supplemental CPR instruction certified by the American Red Cross or the American Heart Association;

(b) EMT-first responder certification;

(c) EMT-A certification; or

(d) Licensure as a registered nurse, physician, or dentist.

Section 5. Requirements for Provision of Services; Diagnostic Services and Treatment Services. (1) Unless an exemption applies, a licensed mobile health service shall comply with the:

(a) Requirements listed in Sections 3, 4, and 6 of this administrative regulation;

(b) Service's program narrative; and

(c) Additional requirements of this section that relate to the particular service offered by the licensee.

(2) Diagnostic services. Diagnostic services are services which are performed to ascertain and assess an individual's physical health condition.

(a) Diagnostic services, except for mammography services, shall be performed only on the order of a physician or advanced practice registered nurse as authorized in KRS 314.011(8).

(b) The licensee shall prepare a record for each patient that includes the following:

1. Date of the procedure;

2. Name of the patient;

3. Description of the procedures ordered and performed;

4. The referring physician;

5. The name of the person performing the procedure; and

6. The date and the name of the physician to whom the results were sent.

(c) Diagnostic imaging services.

1. Diagnostic imaging services shall be services that produce an image through film or computer generated video of the internal structures of a patient. These services may include:

a. X-ray;

- b. MRI;
- c. CT scanning;
- d. PET scanning;
- e. Ultrasound;
- f. Mammography;
- g. Fluoroscopy; and
- h. Other modalities using directed energy to gain statistical, physiological, or biological diagnostic imaging information.

2. A mobile health service that provides diagnostic imaging services shall comply with the following requirements:

- a. Equipment used for direct patient care shall be fully approved by the Federal Food and Drug Administration (FDA) for clinical use;

- b. There shall be a written preventive maintenance program, which the licensee follows to ensure that imaging equipment is:

- (i) Operative;

- (ii) Properly calibrated; and

- (iii) Shielded to protect the operator, patient, environment, and the integrity of the images produced;

- c. Recalibration of radiation producing and nonradiation producing instrumentation shall occur at least every six (6) months by biomedical service personnel; and

- d. Radiation producing instrumentation shall be recalibrated annually by a consulting health physicist.

3. Diagnostic imaging services shall be provided under the supervision of a physician who is qualified by advanced training and experience in the use of the specific imaging technique for diagnostic purposes.

4. Imaging services shall have a current license or registration pursuant to KRS Chapter 311B and 902 KAR Chapter 100.

5. Personnel engaged in the operation of imaging equipment shall be currently licensed or certified in accordance with KRS Chapter 311B and 201 KAR Chapter 46.

6. There shall be a written training plan for personnel in the safe and proper usage of the mobile imaging equipment and system.

7. There shall be a physician's signed order that:

- a. Specifies the reason the procedure is required;

- b. Identifies the area of the body to be examined; and

- c. Documents the condition of the patient.

8. There shall be sufficiently trained on-duty personnel with adequate equipment to provide emergency resuscitation services if there is a patient emergency.

- (d) Other diagnostic services.

1. Other diagnostic services shall be provided through the use of diagnostic equipment and physical examination. These services may include:

- a. Electrocardiogram services;

- b. Electroencephalogram services;

- c. Holter monitor services;

- d. Disability determination services;

- e. Pulmonary function services;

- f. Aphresis services;

- g. Blood gas analysis services;

- h. Echosonography services; and

- i. Doppler services.

2. Equipment used for direct patient care shall comply with the following:

- a. The licensee shall establish and follow a written preventive maintenance program to ensure that equipment shall be operative and properly calibrated;
- b. All personnel engaged in the operation of diagnostic equipment shall have training and be currently licensed or certified in accordance with KRS Chapter 311B and 201 KAR Chapter 46; and
- c. There shall be a written personnel training plan for instruction in the safe and proper usage of the equipment.

3. Physical examination services shall be nonabusive and provided in a manner that ensures the greatest amount of safety and security for the patient.

- a. Protocols for diagnostic examinations shall be developed by the medical director.
- b. Personnel performing physical examinations shall:
  - (i) Have training; and
  - (ii) Be currently licensed or certified in accordance with KRS Chapter 311 or KRS Chapter 314.
- c. Personnel performing physical examinations shall be limited by the relevant scope of practice pursuant to his or her professional license to practice.

(3) Treatment services. Treatment services are services provided to a patient who, because of a physical health condition, is in need of medical assistance for the attainment of his or her maximum level of physical function.

(a) Mobile health clinic.

1. A mobile health clinic shall provide both diagnostic and treatment services through the use of a mobile vehicle that meets the requirements of Section 4 of this administrative regulation.

2. A mobile health clinic may provide a wide range of diagnostic and treatment services on an outpatient basis for a variety of physical health conditions.

3. Policies. The licensee shall develop patient care policies with the advice of a group of professional personnel that includes:

- a. One (1) or more physicians; and
- b. One (1) or more advanced practice registered nurses.

4. At least one (1) member of the group responsible for developing patient care policies shall not be a member of the mobile health clinic staff.

5. The policies shall include:

- a. A description of the services the mobile health clinic provides directly and those provided through agreement;
- b. Guidelines for the medical management of health problems, which include the conditions requiring medical consultation or patient referral, and the maintenance of health records; and
- c. Procedures for review and evaluation of the services provided by the clinic at least annually.

6. Personnel. The mobile health clinic shall have a staff that includes:

- a. At least one (1) physician;
- b. At least one (1) advanced practice registered nurse; and
- c. Other staff or ancillary personnel that are necessary to provide the services essential to the clinic's operation.

7. The physician shall:

- a. Be responsible for all medical aspects of the clinic;
- b. Provide direct medical services in accordance with the Medical Practice Act, KRS Chapter 311;
- c. Provide medical direction, supervision, and consultation to the staff;

- d. In conjunction with the advanced practice registered nurse, participate in developing, executing, and periodically reviewing the mobile health clinic's written policies and services;
- e. Periodically review the mobile health clinic's patient records, provide medical orders, and provide medical care services to patients of the mobile health clinic; and
- f. Be present for consultation weekly, and be available within one (1) hour, through direct telecommunication for consultation, assistance with medical emergencies, or patient referral.

8. The advanced practice registered nurse shall:

- a. Participate in the development, execution, and periodic review of the written policies governing the services the mobile health clinic provides;
- b. Participate with the physician in periodic review of patient health records;
- c. Provide services in accordance with mobile health clinic policies, established protocols, the Nurse Practice Act, KRS Chapter 314 and 201 KAR Chapter 20;
- d. Arrange for, or refer patients to needed services not provided at the mobile health clinic; and
- e. Assure that patient health records are maintained and transferred when patients are referred.

9. The mobile health clinic shall have linkage agreements or arrangements with each of the following:

- a. Inpatient hospital care;
- b. Physician services in a hospital, patient's home, or long-term care facility;
- c. Additional and specialized diagnostic and laboratory services that are not available at the mobile health clinic;
- d. Home health agency;
- e. Emergency medical services;
- f. Pharmacy services; and
- g. Local health department.

10. The mobile health clinic shall:

- a. Carry out or arrange for an annual evaluation of its total program; and
- b. Consider the findings of the evaluation and take corrective action, if necessary. The evaluation shall include:
  - (i) The utilization of clinic services including at least the number of patients served and the volume of services;
  - (ii) A representative sample of both active and closed clinical records; and
  - (iii) The mobile health clinic's health care policies.

11. The mobile health clinic shall develop and maintain written protocols that include standing orders, rules of practice, and medical directives that:

- a. Apply to services provided by the clinic; and
- b. Explicitly direct the step-by-step collection of subjective and objective data from the patient. The protocols shall:
  - (i) Direct data analysis;
  - (ii) Direct explicit medical action depending upon the data collected;
  - (iii) Include rationale for each decision made; and
  - (iv) Be signed by the staff physician.

12. The mobile health clinic staff shall furnish diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at the entry point into the health care delivery system, including:

- a. Medical history;
- b. Physical examination;
- c. Assessment of health status; and

d. Treatment for a variety of medical conditions.

13. The mobile health clinic shall provide basic laboratory services essential to the immediate diagnosis and treatment of the patient, including:

a. Chemical examinations of urine by stick or tablet methods or both, including urine ketones;

b. Microscopic examinations of urine sediment;

c. Hemoglobin or hematocrit;

d. Blood sugar;

e. Gram stain;

f. Examination of stool specimens for occult blood;

g. Pregnancy tests;

h. Primary culturing for transmittal to a hospital laboratory or licensed laboratory; and

i. Test for pinworms.

14. The mobile health clinic shall:

a. Provide medical emergency procedures as a first response to common life-threatening injuries and acute illness; and

b. Have available the drugs and biologicals commonly used in lifesaving procedures, including:

(i) Analgesics;

(ii) Anesthetics (local);

(iii) Antibiotics;

(iv) Anticonvulsants;

(v) Antidotes;

(vi) Emetics;

(vii) Serums; and

(viii) Toxoids.

15. The mobile health clinic shall post the following in a conspicuous area at the entrance, visible from the outside of the clinic:

a. The hours that emergency medical services will be available in the clinic;

b. The clinic's next scheduled visit; and

c. Where emergency medical services not provided by the clinic can be obtained during and after the clinic's regular scheduled visits and hours of operation.

(b) Mobile dental clinic.

1. A mobile dental clinic shall provide both diagnostic and dental treatment services at different locations through the use of a mobile vehicle or equipment.

2. Policies. The licensee shall develop patient care policies with the advice of a group of professional personnel that includes at least one (1) licensed dentist.

3. The policies shall include:

a. Guidelines that identify dental problems beyond the scope of services provided by the licensee;

b. Provisions for patient referral;

c. Guidelines for the review and evaluation of the services provided by the clinic at least annually;

d. Procedures to be followed if a patient has a medical emergency; and

e. Guidelines for infection control.

4. Personnel. The mobile dental clinic shall have a staff that includes at least:

a. One (1) licensed dentist; and

b. One (1) dental assistant.

5. The dentist shall:

- a. Be responsible for all aspects of patient care in accordance with KRS Chapter 313 and 201 KAR Chapter 8;
  - b. Be present in the clinic at all times that a patient is receiving dental care; and
  - c. Provide direct supervision to all staff involved in the delivery of services.
6. The dental assistant shall:
- a. Provide services in accordance with:
    - (i) The mobile dental clinic policies and established protocols; and
    - (ii) KRS Chapter 313 and 201 KAR Chapter 8; and
  - b. Provide services only under the direct supervision of a licensed dentist.
7. Equipment. The mobile dental clinics shall have the following equipment:
- a. X-ray units;
  - b. Sterilizer;
  - c. High-speed suction;
  - d. Dental lights; and
  - e. Emergency kit with the following drug types:
    - (i) Antiallergenic;
    - (ii) Vasodilators;
    - (iii) Anticonvulsives; and
    - (iv) Vasopressors.
  - (c) Mobile lithotripter service.
1. A mobile lithotripter service shall provide a noninvasive technique for removing kidney or ureteral stones through the use of a lithotripter at various hospital locations.
2. Mobile lithotripter services may only be delivered on the grounds of the hospital utilizing the mobile lithotripter service.
3. Lithotripsy services shall be:
- a. Performed only on the order of a physician; and
  - b. Provided under the supervision of a physician who is qualified by advanced training and experience in the use of lithotripsy treatment.
4. The mobile lithotripter service shall prepare a record for each patient that includes the:
- a. Date of the procedure;
  - b. Name of the patient;
  - c. Description of the procedures ordered and performed;
  - d. Referring physician; and
  - e. Name of the person performing the procedure.
5. There shall be a physician's signed order that specifies the:
- a. Reason the procedure is required;
  - b. Area of the body to be exposed; and
  - c. Anticipated outcome of treatment.
6. Policies. A mobile lithotripter service shall develop patient care policies with the advice of a group of professional personnel that includes at least:
- a. One (1) qualified urologist; and
  - b. One (1) qualified anesthetist.
7. At least one (1) member of the group responsible for developing patient care policies shall not be a member of the mobile lithotripter service staff.
8. The policies shall include:
- a. A description of how a patient will be transported between the hospital and the mobile lithotripter service;
  - b. Procedures to be followed if a patient has a medical emergency;
  - c. Guidelines for the review and evaluation of the service on an annual basis; and

d. Policies and protocols governing the utilization and responsibilities of hospital staff in the delivery of lithotripter services.

9. Personnel. The mobile lithotripter service shall:

a. Employ at least one (1) lithotripter technician; and

b. Employ or make arrangements with the hospital utilizing the service for at least:

(i) One (1) registered nurse and one (1) qualified urologist to be present in the unit during the delivery of lithotripsy services; and

(ii) One (1) qualified anesthetist to be available for procedures requiring anesthesia.

10. Lithotripsy equipment used for direct patient care shall comply with the following:

a. Lithotripsy equipment shall be fully approved by the Federal Food and Drug Administration (FDA) for clinical use;

b. The licensee shall establish and follow a written preventive maintenance program to ensure that equipment shall be:

(i) Operative;

(ii) Properly calibrated;

(iii) Properly shielded; and

(iv) Safe for the patient, operator, and environment.

11. All personnel engaged in the operation of diagnostic equipment shall have training and be currently licensed, certified, or registered in accordance with KRS Chapter 311B and 201 KAR Chapter 46.

12. There shall be a written training plan for the training of personnel in the safe and proper usage of the equipment.

13. There shall be trained on-duty personnel with equipment to provide emergency resuscitation if there is a patient emergency.

(d) Therapy practices. A therapy practice licensed pursuant to this administrative regulation shall:

1. Develop patient care policies that:

a. Include a description of services provided directly or through an agreement;

b. Include guidelines for the medical management of health problems that include the conditions requiring medical consultation or patient referral;

c. Address clinical records;

d. Include procedures for review and evaluation of the services provided at least annually; and

e. Ensure that physical therapy, occupational therapy, and speech pathology services shall be provided within the professional scope of practice established in KRS Chapter 327, KRS Chapter 319A, and KRS Chapter 334A, respectively;

2. Employ a sufficient number of qualified personnel pursuant to Section 3(5) of this administrative regulation;

3. Maintain a written plan of care for each patient that:

a. Indicates anticipated goals;

b. Specifies the type, amount, frequency, and duration of:

(i) Physical therapy;

(ii) Occupational therapy; or

(iii) Speech pathology;

c. Is established by the:

(i) Physical therapist who will provide physical therapy services;

(ii) Occupational therapist who will provide occupational therapy; or

(iii) Speech-language pathologist who will provide speech pathology services; and

4. Except for Section 3(4)(a) and, if applicable, Section 3(9) of this administrative regulation,

demonstrate compliance with Section 2 and Section 3 of this administrative regulation, in addition to the requirements of this paragraph. Section 4 and Section 6 of this administrative regulation, and subsection (2) through subsection (3)(a), (b), (c), and (e) of this section shall not apply to a therapy practice licensed pursuant to this administrative regulation.

(e)1. Other treatment services shall:

- a. Be performed only on the order of a physician;
- b. Demonstrate compliance with the policy, personnel, in-service training, and program evaluation requirements established in subparagraphs 4. through 11. of this paragraph; and
- c. May include IV therapy services. If provided, IV therapy shall:
  - (i) Only be performed by a registered nurse; and
  - (ii) Be limited to nursing services that are required for the initial start-up of an IV therapy program.

2. If nursing services are required that exceed the initial start-up of IV therapy, the services shall be provided by an agency that is licensed to provide care under a physician's plan of care.

3. All services provided shall be under the supervision of a licensed physician.

4. Policies. The licensee shall develop patient care policies with the advice of a group of professional personnel that includes at least:

- a. One (1) physician; and
- b. One registered nurse.

5. At least one (1) member of the group responsible for developing patient care policies shall not be a member of the service's staff.

6. The policies shall include:

- a. A description of the services provided;
- b. A requirement to inform patients of other in-home services which can be provided only by other licensed agencies;
- c. A requirement for a written common plan for treatment and coordination of treatment with other licensed health care providers delivering services to the patient. Immediate verbal communication between providers regarding revisions to the common plan shall be documented in the plan of treatment;
- d. Guidelines for the medical management of health problems, including:
  - (i) The conditions requiring medical consultation or patient referral; and
  - (ii) Maintenance of health records;
- e. Procedures for review and evaluation of the services provided at least annually; and
- f. Guidelines for patient and environment assessment.

7. Personnel. The service shall have a staff that includes at least one (1) registered nurse.

8. The service shall employ other staff or ancillary personnel that are necessary and essential to the service's operation.

9. The registered nurse shall:

- a. Participate in the development, execution, and period review of the written policies governing the services provided;
- b. Participate with the physician in periodic review of patient health records;
- c. Provide services in accordance with established policies, protocols, the Nurse Practice Act, KRS Chapter 314 and 201 KAR Chapter 20;
- d. Arrange for or refer patients to needed services that cannot be provided by the service; and
- e. Assure that patient health records are maintained and transferred when patients are referred.

10. In-service training programs shall include instruction in:

- a. Use of equipment;
- b. Side effects and precautions of drugs and biologicals; and
- c. Infection control measures.

11. The service shall:

- a. Carry out, or arrange for an annual evaluation of its total program;
- b. Consider the findings of the evaluation; and
- c. Take corrective action, if necessary. The evaluation shall include:
  - (i) The utilization of the service including the number of patients served and the volume of services;
  - (ii) A representative sample of both active and closed records; and
  - (iii) The service's health care policies.

Section 6. Waste Processing. (1) Sharp wastes, including broken glass, scalpel blades, and hypodermic needles, shall be segregated from other wastes and placed in puncture-resistant containers immediately after use.

(2) A needle or other contaminated sharp waste shall not be recapped, purposefully bent, broken, or otherwise manipulated by hand as a means of disposal except as permitted by the Centers for Disease Control and the Occupational Safety and Health Administration guidelines at 29 C.F.R. 1910.1030(d)(2)(vii).

(3) A sharp waste container shall be incinerated on or off-site or rendered nonhazardous.

(4) Any nondisposable sharp waste shall be placed in a hard walled container for transport to a processing area for decontamination.

(5)(a) Disposable waste shall be:

- 1. Placed in a suitable bag or closed container so as to prevent leakage or spillage; and
- 2. Handled, stored, and disposed of in a way that minimizes direct exposure of personnel or patients to waste materials.

(b) The licensee shall establish specific written policies regarding handling and disposal of waste material.

(6) All unpreserved tissue specimens shall be incinerated off site. (23 Ky.R. 2645; Am. 2999; eff. 1-15-1997; TAm eff. 3-11-2011; TAm eff. 12-10-2012; 42 Ky.R.2275, 2735; eff. 6-3-2016.)